PUBLIC HEALTH COUNCIL

A regular meeting of the Public Health Council of the Massachusetts Department of Public Health was held on May 23, 2006, 10:00 a.m., at the China Trade Center, 2 Boylston Street, Daley Conference Room, Boston, Massachusetts. Public Health Council Members present were: Chair Paul J. Cote, Jr., Clifford Askinazi, M.D., Michael C. Hanson, Soo J. Kim, Jennifer A. Nassour, Maureen Pompeo, Albert Sherman (arrived late at 10:10 a.m.), and Martin J. Williams, M.D. Gaylord B. Thayer, Jr. was absent. Also in attendance was Attorney Donna Levin, General Counsel.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He further announced that the Council would hear the proposed regulations (docket items 2a, 2b, and 2c) prior to the staff presentation.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control; Attorney Silva Cameron, Office of Emergency Medical Services, Ms. Joan Gorga, Acting Director, Mr. Jere Page, Senior Program Analyst, and Bernard Plovnick, Consulting Program Analyst, Determination of Need Program.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETING OF MARCH 21, 2006:

Records of the Public Health Council Meeting of March 21, 2006 were presented to the Council for approval. After consideration, upon motion made and duly seconded, it was voted (unanimously)[Council Member Albert Sherman not present to vote] to approve the Records of the Public Health Council Meeting of March 21, 2006 as presented.

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 130.000; HOSPITAL LICENSURE, AND 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, FOR MEDICAL CONTROL SERVICE:

Dr. Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control, presented the proposed amendments to 105 CMR 130.000 to the Council. He said in part, "…These regulations implement a section of EMS 2000, which is a major reform of the system by which pre-hospital services are provided in Massachusetts to assure that pre-hospital personnel have appropriate oversight from hospital-based physicians. The regulations create a new category in Hospital Licensure regulations; a new service called a Medical Control Service, and amends the EMS regulations, the Ambulance Licensing regulations to bring them into conformance with the new requirement for the medical control regulations."

The details of the proposed regulations are set out in the Council memorandum dated May 23, 2006, as follows:

"The Medical Services subcommittee proposed a set of medical control improvement recommendations, which were supported by the Emergency Care Advisory Board (EMCAB)'s Executive Committee. Based on these recommendations, the Department developed draft amendments to 105 CMR 130.000 and met several times with EMCAB's subcomittee and presented the final version to the full EMCAB for their review and comment. The comments have been incorporated as appropriate into the proposed regulations."

Establishment of "Medical Control Services"

The organized provision of medical control by a hospital to an EMS service in accordance with the regulatory standards, as a new service for which a hospital may seek to be licensed. These include designation of an affiliate hospital medical director; provision of medical control data to the Department; making available to EMS personnel on-line medical direction 24 hours a day; ensuring a process for skill maintenance and review, providing remedial training opportunities in the hospital emergency department and in operating rooms and skill laboratories; operating an effective QA/QI program for the EMS service in accordance with the hospital's own QA/QI standards and protocols; and making available hospital emergency department physicians and nurses to meet with EMS personnel in morbidity and mortality rounds and chart reviews. These provisions largely mirror affiliate agreement provisions found in 105 CMR 170.000.

Enhancement of Duties of Affiliate Hospital Medical Director

These amendments further define the duties of an affiliate hospital medical director in addition to those currently set out in 105 CMR 170.300 and require the hospital to ensure that the medical director performs those duties. These duties begin with ensuring the clinical competence of EMS personnel and authorizing them to practice. The Department certifies EMS personnel, but in addition, EMS personnel certified at the ALS level must be authorized to practice by their EMS service's affiliate hospital medical director. The amendments also make affiliate hospital medical directors responsible for ensuring that all physicians providing on-line medical direction to EMS personnel do so in conformance with the Statewide Treatment Protocols, which set out the clinical practice standards for EMS personnel. This includes the responsibility for providing appropriate orientation to these physicians to make sure that they are conversant with EMS practice, including local EMS providers. The amendments also hold affiliate hospital medical directors responsible for coordinating the QA/QI program, providing information to the Regional Medical Director and maintaining their own skills and knowledge in EMS care through continuing education.

Establishment of Standards for Physicians Involved in Medical Control:

The proposed amendments for the first time establish qualifications for affiliate hospital medical directors as well as on-line medical control physicians, which hospitals must ensure are met. Under these proposed amendments, on-line medical direction physicians must be currently credentialed to practice in a Massachusetts hospital emergency department, and must demonstrate proficiency in the clinical application of the current Statewide Treatment Protocols. They must be proficient in EMS radio communications. In addition to meeting the same requirements as on-line medical direction physicians, the affiliate hospital medical directors must be board-certified in emergency medicine.

Changes in Emergency Medical Services System Regulations:

These amendments make changes to 105 CMR 170.000, the Emergency Medical Services System regulations, for consistency with the amendments to 105 CMR 130.000. The proposed amendments to 105 CMR 170.000 clarify the existing provision that permits ambulance services to have more than one affiliation agreement, by limiting this to services that operate in more than one EMS region, and with Department approval only to services with more than one place of business in a single region. Because the proposed amendments to 105 CMR 130.000 also require affiliate hospital medical directors to report to the Department within 48 hours any adverse action regarding an EMTs or EFRs authorization to practice, including the remediation plan for the individual, this reporting is added to 105 CMR 170.795 as a complaint that will trigger an investigation by the Department.

A public hearing will be held on June 26, 2006 to receive comments on these proposed amendments. Following the hearing, the Department staff will return to the Council with a review of the testimony and to present any changes proposed in response to the testimony and to request approval for promulgation of the final proposed amendments.

No Vote/Information Only

INFORMATIONAL MEMORANDUM REGARDING AMENDMENTS TO 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, FOR STATEWIDE EMS DATA COLLECTION

Attorney Silva Cameron, Office of Emergency Medical Services, presented the proposed amendments to 105 CMR 170.000 to the Council, "…The proposed amendments make a change to the current ambulance trip record minimum data requirement, to implement a comprehensive statewide EMS data collection that is compliant with the National EMS Information System Dataset (NEMSIS), a national standard that virtually all the states have committed to adopting, and some have already implemented. The benefits of such a data collection system include greatly enhanced quality assurance and quality improvement of all aspects of ambulance service operations and the delivery of patient care by the EMS system."

The amendments propose the following:

- Delete existing general categories of elements that 105 CMR 170.345 currently require be included, as a minimum, in each ambulance trip record, and instead requires the trip record contain the data elements specified in an administrative requirement of the Department…The proposed minimum data set is tied to a federal standard, the Department is setting it out in a sub-regulatory document, so amendment to comply with updated versions of the federal standard is facilitated.

- Under the draft administrative requirement, for an interim period, ambulance services would continue to collect as a minimum data set the same general categories of elements as they do under the current regulations, until the Department officially implements the date on which all ambulance services would need to collect the proposed statewide NEMSIS-compliant minimum data set. Based on data from other states' experience, the Department expects it to take one to two years to build the data system.

- During the interim period, some larger ambulance services will participate in a pilot program to collect the full statewide minimum data set (400 NEMSIS data elements).

- The data set includes data related to the responding ambulance, dispatch of that ambulance, times, scene information, patient care information, relevant medical history information, specific elements for trauma or cardiac arrest incidents, interventions performed, hospital destination and outcome linkage information. Many ambulance services are now collecting more than the 126 elements in this proposed data set.

Staff memorandum to the Council, dated May 23, 2006, states, "…This proposal implements a requirement long identified to the Department by EMS stakeholders – the collection of comprehensive, standardized EMS data across Massachusetts – in order to do effective quality assurance /quality improvement on all aspects of the provision of ambulance service and prehospital patient care. Moreover, having this data about EMS performance in Massachusetts will provide a stronger foundation for EMS training, Statewide Treatment Protocols and policy development. Moving to do this by adopting a NEMSIS-compliant model achieves the even better result of joining nearly all the other U.S. states in collecting standardized EMS data across the nation…"

A public hearing will be held on June 26, 2006 to receive comments on the proposed amendment. Following the hearing, Department staff will return to the PHC to provide a review of the testimony, to present any changes proposed in response to the testimony, and to request approval for promulgation of the amendment.

No Vote/Information Only

INFORMATIONAL BRIEFING: FOLLOW-UP ON 105 CMR 130.000, HOSPITAL LICENSURE, MATERNAL AND NEWBORN REGULATIONS:

Paul Cote, Chair of the Public Health Council and Commissioner, Department of Public Health, gave a briefing on the maternal and newborn regulations, specifically about the distribution of free formula bags to mothers in maternity wards of hospitals in Massachusetts. He said, "…I am going to present the update on this matter. As you may recall, as discussed at the February 21 Public Health Council Meeting, the Department has reviewed its Perinatal Care Regulations with respect to the provisions of so-called gift bags including infant formula samples to new parents on discharge. As a result of this review, we understand that the current regulations as they stand require that each maternal and newborn service must develop and implement written patient care policies and procedures that include provision for support of lactation initiation and maintenance for mothers who choose breast feeding, and the current regulations require that such policies must ensure that sample formula and/or formula equipment be distributed to breast feeding mothers only when an individual physician order is written or upon the request of the mother."

Chair Cote continued, "Current regulation does not limit the ability of any mother, in consultation with her physician, to choose the feeding method for her infant, or prohibit hospitals from providing formula to infants upon discharge when the mother requests it, or the hospital or a physician determines that it is appropriate for that particular infant. Based on this, it is our conclusion that the current regulations provide adequate support for mothers who choose breast feeding, while recognizing that alternatives may sometimes be necessary. Accordingly, the Department is not recommending any further changes to these regulations."

Council Member Maureen Pompeo added, "think that is a good compromise…I don't mean bureaucratic in a negative way, but it was a bureaucratic process that led to the review of this without any real exchange of information about whether or not it should be in the regulations at all."

No Vote/Information Only

STAFF PRESENTATION: "BACKGROUND ON THE DETERMINATION OF NEED PROGRAM", by Paul Dreyer, Ph.D., Associate Commissioner, Center for Quality Assurance and Control and Joan Gorga, Acting Director, Determination of Need Program, made a slide presentation on the DoN Program. Some excerpts from the presentation follow:

- The Determination of Need Program was established in 1972 by state statute, M.G.L.c.111,25C, and was later mandated nationally, in 1974, under Public Law 93-641, which is The National Health Planning and Resources Development Act of 1974.

- The National Health Planning and Resources Development Act of 1974 created a health planning structure. It funded and created an Office of State Health Planning(OSHP) in all US states. They were called State Health Plan Development Agencies (SHPDA) which created and funded the HSAs (Health Service Areas).

- In the early 1970s, hospital reimbursement was based on a retrospective review of cost reports. Hospitals were reimbursed for their costs with inflation. There was no incentive to constrain costs. The belief at the time was a bed built would be a bed filled because the reimbursement system incentives were on maximizing utilization. The belief at the time to constrain costs was to constrain utilization, thus the DoN program was born.

- In 1975, the DoN program had thirty employees. They reviewed acute care bed need, long term care bed need, and mental health bed need. The OSHP issued guidelines, population-based utilization rates for appropriate levels of service and then hospitals and other health care providers filed Determination of Need Applications to try to respond to the need that was projected in the planning documents. This resulted in competing applications and staff and the Public Health Council would have to chose the more worthy applicant/s.

- In the 1980s, the DRG System (Diagnostic Related Groups) began. Medicare reimbursement changed. The goal was to reduce utilization in order to maximize reimbursement as opposed to the previous system.

- In 1998, the federal State Health Planning Law was repealed and State Law made major changes to the DoN Program. It deregulated acute care bed need so that, after 1998, hospitals could build as many beds as they chose without regulation. There were recommendations at the time for consideration of using licensure as an alternative means to maintain controls on supply as opposed to DoN. Accordingly, we removed cardiac catheterization from the list of DoN regulated services and transitioned it over to a licensure approach. In 1998, we deregulated bone marrow transplant, both autologous and allogeneic.

- At the present time, DoN regulates in the area of capital expenditure, acute care facilities in excess of $12,516,300; and for clinics in excess of $667,535 for equipment. For non-acute care facilities, those with plans in excess of $1,335,072 for capital expenditure. These figures are indexed for inflation so that they change each year. DoN regulates Change of Ownerhip for hospitals and for ambulatory surgery centers. For innovative services and new technologies, DoN regulates air ambulance services, extracorporeal membrane oxygenation (ECMO), open heart surgery (not accepting applications for this due to no need at this time) MRI (accepting applications from existing providers only), and Neonatal Intensive Care Units (NICUs) (not accepting applications until August of 2007). DoN also regulates Organ Transplantation, Positron Emission Tomography (PET) and Radiation Therapy Services (applications accepted from existing providers only).

In Long Term Care, DoN regulates new beds, however no applications are being accepted until 2010 due to no need. DoN regulates renovation and replacement of long term care facilities (these applications can be filed anytime on any business day). DoN further regulates original hospital licensure and original ambulatory surgery center licensure. Lastly, together with the Bureau of Substance Abuse, DoN regulates detox facilities; halfway houses and treatment facilities.

- The DoN program has transitioned from constraining costs to a program whose focus has moved towards maintaining quality.

- Acute care hospitals filing for capital projects must make a contribution to community programs (referred to as Linkage or Community Health Initiatives). Linkage is usually 5% of the maximum capital expenditure (MCE) of the project.

- In 1996, over 50% of the Linkage money was spent on facilities and equipment. Presently, the Department has gone to a system of grants to community agencies through direct funding to the Community Health Network Areas (CHNAs). The Department's Office of Healthy Communities negotiates with the applicants about where the Linkage funds should be spent.

- In 1991 for MRI and 1993 for other technologies, the Legislature closed the loophole that allowed physicians (but not hospitals) to acquire technologies without going through the DoN process. However, physicians had a chance to file a Letter of Intent to acquire technology prior to the 1991 and 1993 enactment dates allowing them still today to acquire technology without going through the DoN process if they hold such a letter (physician exemption letter).

- Under 105 CMR 100.308 of the Determination of Need Regulations, there are special exemptions which the DoN Director may grant to an applicant which allows the applicant to have, for instance, a MRI for one year without a DoN approval. If the applicant wishes to continue the program beyond that time, it must file a DoN application for the project prior to the end of that first year. The project will be reviewed under the normal standards and criteria for that type of application. Any 308 exemption granted shall in no way constitute evidence of need for a project.

No Vote/Information Only

DETERMINATION OF NEED PROGRAM:

CATEGORY 1 APPLICATION:

PROJECT APPLICATION NO. 4-3B03 OF BRIGHAM AND WOMEN'S HOSPITAL - To provide transplantation services as part of the New England Pancreas Consortium:

Ms. Joan Gorga, Acting Director, Determination of Need Program, made introductory comments and answered some of the Council's questions. Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the Brigham and Women's Hospital application to the Council. Some excerpts from his presentation and the staff summary follow:

"Based on the existing and projected utilization, Staff finds need for an additional program in pancreas transplantation in Massachusetts to be located at Brigham and Women's Hospital as part of the New England Pancreas Consortium (NEPC). Staff has determined that the Hospital's projected volume of 10 pancreas transplants in FY 2007 and 11 transplants in FY 2008, is based on reasonable assumptions, including the potential transplant volume in Massachusetts as indicated in 2010 population-based estimates, the current Region 1 waiting list, as well as the estimated number of pancreases available for transplant in Region 1. In addition Staff notes that, as conditions of approval, the Hospital will provide Medicaid access and free care as required and has not reduced Medicaid intensive services to non-transplant patients."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve **Project Application No. 4-3B03 of Brigham and Women's Hospital** to provide pancreas transplantation services as part of the New England Pancreas Consortium, based on staff findings, with a maximum capital expenditure of $0 and estimated first year incremental operating costs of $513,280 (August 2005 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14, 858**. As approved the application provides for a pancreas transplant service at BWH as part of NEPC. This Determination is subject to the following conditions:

1. This approval for pancreas transplantation services is contingent on the continued cooperation of Brigham & Women's Hospital (BWH) as set forth in the Memorandum of Understanding of the NEPC.

2. BWH shall participate in the NEPC Central Selection Committee to evaluate and select final candidates for pancreas transplantation. The Central Selection Committee shall hear appeals of any patients who believe they have been improperly eliminated in the pre-screening process by Brigham and Women's.

3. BWH shall use, and each patient shall meet, the selection criteria as described in the NEPC application Section IV: Recipient Selection Criteria, which was approved in June 1997 (Project No. 4-3926). Any changes in these criteria must

be submitted to the Commissioner, Department of Public Health, for approval. Any patient who is proposed for pancreas transplantation who does not meet each of the patient selection criteria shall be reviewed by the Administrative Committee of the NEPC.

4. BWH shall publish in the patient informational material provided to each patient on the kidney-pancreas and pancreas transplant procedure, the kidney-pancreas and pancreas transplant survival rates of the applicable facility as well as the average transplant survival rate of the NEPC.

5. BWH shall collect the clinical and cost data involved with the Hospital's pancreas transplant program in such format as requested by the Department of Public Health on an annual basis.

6. BWH shall enter into referral arrangements for provision of pancreas transplantation with any acute care hospital in New England which desires such an arrangement.

7. For Massachusetts residents, BWH shall not consider ability to pay or insurance status in the evaluation or recipient selection process. Massachusetts residents who are uninsured or are insured through government programs shall have equal access to transplants. Free care will be provided to non-Massachusetts residents by the Hospital in accordance with existing hospital-free care policies.

8. BWH shall not reduce Medicaid intensive services or procedures, or primary care services or procedures as a trade-off for pancreas transplants.

9. BWH shall not, as a consequence of its undertaking a pancreas transplant program, reduce the amount of the free care provided to patients who have not received pancreas transplant services below the amount provided during the Hospital's 2005 fiscal year, as adjusted for inflation.

10. BWH shall have its pancreas transplant protocols, including consent or withdrawal of consent policies, organ procurement policies and confidentiality policies, reviewed and approved by the NEPC Ethics Committee.

11. BWH shall be reimbursed $51,328 (August 2005 dollars) for each pancreas-only transplant. Future increases in organ acquisition fees will routinely be added to the per transplant reimbursement. Inflation factors calculated by the Division of Health Care Finance and Policy will be used to reassess the reimbursement for transplants and retransplants annually.

Staff's recommendation was based on the following findings:

1. Based on staff's analysis and findings noted in the staff summary, staff recommends approval with conditions of Project No. 4-3B03 filed by BWH to

provide pancreas transplantation services at the Hospital as part of the New England Pancreas Consortium.

2. The health planning process for the project was satisfactory.

3. Need exists for a program in pancreas transplantation at BWH based on projected utilization, as discussed under the health care requirements section of the staff summary.

4. BWH has met the conditions placed on the 1991 temporary DoN approval including free care, Medicaid access and nondiscrimination on the basis of ability to pay. The other previous conditions One, Three, Four, Six, Seven, Eight, Nine, Ten, Eleven, Twelve, and Thirteen should continue to apply.

5. NEPC member hospitals in Massachusetts have equaled or surpassed the average national survival rates for pancreas transplantation.

6. BWH is certified by the Medicare Program to perform kidney transplantation and therefore met the eligibility standards of the Department.

7. The project, with adherence to certain conditions, has met the operational objectives of the DoN Regulations.

8. The project satisfies the compliance standards for the service, and Brigham and Women's will comply with the Department's Hospital Licensure Regulations.

9. No capital expenditure is associated with this project.

10. The incremental operating costs of $513,280 (August 2005 dollars) are reasonable based on an estimated cost of $51,328 each for the ten pancreas-only transplants anticipated in FY 2007, the first full year of operation. All operating costs are subject to review by the Division of Health Care Finance and Policy (DHCFP) according to its policies and procedures. The per transplant cost should be reassessed annually by the DHCFP according to its policies on inflation.

11. The project is financially feasible and within the financial capability of the Hospital.

12. The project satisfies the requirements for relative merit.

13. The NEPC, including BWH, participated in the Community Health Initiatives program involved with the 1991 temporary DoN approval, and has fulfilled its recommended responsibilities. Therefore, Staff is not recommending an additional community initiatives be added to the present project.

This meeting adjourned at 10:50 a.m.

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Paul J. Cote, Jr., Chair

LMH/lmh